OVERVIEW OF THE BUDGET REQUEST

The fiscal year (FY) 2015 President's Budget Request for FDA is $4.74 billion for the total Program Level, which is $358 million above the FY 2014 Enacted level. Of the total funding, $2.58 billion is budget authority and $2.16 billion is user fees. The FY 2015 increase consists of $23 million in budget authority and $335 million in user fees. The growth in user fee funding stems from several new programs, along with increased collection authority for many of FDA's existing programs.

FDA is facing an environment of dramatic technological and market-based changes that require new ways of responding to the market place. FDA has carefully targeted FY 2015 investments to strengthen oversight of the pharmacy compounding industry, support food safety and implementation of FSMA, advance medical countermeasures, and maintain the integrity of operations and infrastructure.

Food and Drug Administration
Major Activities
(Dollars in Thousands)

Program	FY 2014 Enacted				FY 2015 President's Budget				FY 2015 +/- FY 2014			
	Food Safety	Medical Product Safety	Medical Counter-measures	Total*	Food Safety	Medical Product Safety	Medical Counter-measures	Total*	FS	MPS	MCM	Total*
Budget Authority:												
Salaries and Expenses Account												
Foods	882,817			882,817	903,403			903,403	20,586			20,586
Human Drugs		460,354	6,020	466,374		473,658	6,020	479,678		13,304	---	13,304
Biologics		208,533	2,395	210,928		207,359	2,395	209,754		-1,174	---	-1,174
Animal Drugs and Feeds	112,892	28,674		141,566	113,869	30,708		144,577	977	2,034		3,011
Devices and Radiological Health		316,824	4,001	320,825		313,936	4,001	317,937		-2,888	---	-2,888
National Center for Toxicological Research.	10,233	52,261		62,494	5,900	53,098		58,998	-4,333	837		-3,496
FDA Headquarters	70,331	81,464	10,312	172,107	73,285	81,763	10,312	175,360	2,954	299	---	3,253
FDA White Oak Consolidation		58,044		58,044		43,044		43,044		-15,000		-15,000
Other Rent and Rent Related	36,503	37,235	936	74,674	36,682	35,703	911	73,296	179	-1,532	-25	-1,378
GSA Rental Payments	75,341	85,847	888	162,076	78,622	89,849	865	169,336	3,281	4,002	-23	7,260
Subtotal, Salaries and Expenses Account...	**1,188,117**	**1,329,236**	**24,552**	**2,551,905**	**1,211,761**	**1,329,118**	**24,504**	**2,575,383**	**23,644**	**-118**	**-48**	**23,478**
Building and Facilities Account...				**8,788**				**8,788**				---
Total Budget Authority...	**1,188,117**	**1,329,236**	**24,552**	**2,560,693**	**1,211,761**	**1,329,118**	**24,504**	**2,584,171**	**23,644**	**-118**	**-48**	**23,478**
Total User Fees...	**29,559**	**1,255,128**		**1,825,965**	**269,310**	**1,316,562**		**2,160,827**	**239,751**	**61,434**	---	**334,862**
Total Program Level...	**1,217,676**	**2,584,364**	**24,552**	**4,386,658**	**1,481,071**	**2,645,680**	**24,504**	**4,744,998**	**263,395**	**61,316**	**-48**	**358,340**

* Total contains China Initiative, Building and Facilities Account, Family Smoking Prevention and Tobacco Control Act, and Color Certification resources not included in Food Safety, Medical Product Safety, and Medical Countermeasures actitities.

** ADUFA and AGDUFA are currently included in Medical Product Safety. However, ADUFA and AGDUFA also support drug review for food producing animals.

PROGRAM CHANGES:

Medical Product Safety (+$61 million)

The FY 2015 Budget provides a program level of $2.6 billion, which is $61 million above the FY 2014 Enacted level, to continue core medical product safety activities across FDA programs. Within this amount, FDA will invest $25 million in budget authority to enhance pharmacy compounding oversight activities in FY 2015, which will significantly benefit public health and safety. This request also includes $4.6 million for proposed International Courier user fees.

Pharmacy Compounding

In 2012, a fungal meningitis outbreak associated with a compounded sterile drug resulted in 64 deaths and over 750 cases of infections across 20 States. Since September 26, 2012, FDA is aware that 28 firms ceased sterile operations, in some cases voluntarily after FDA inspections, and in other cases due to partial or full shutdowns imposed by state licensing authorities. Since that time, FDA has also learned of at least 20 compounders that may have shipped contaminated drug products, and FDA has received at

least 125 reports of adverse events, including serious infections, associated with drugs produced by compounders. As of February 18, 2014, 33 firms had conducted recalls overseen by FDA and seven firms had conducted recalls overseen by a State. These statistics demonstrate the magnitude of the problems that continue to be seen with compounders' sterile operations. Oversight of these firms requires significant FDA resources to investigate and take action to protect consumers. Further, in November 2013, President Obama signed the Drug Quality and Security Act (DQSA), Public Law 113-54, which provides FDA with additional responsibilities to oversee compounding activities. This is a major public health focus for FDA.[1]

During FY 2013, in response to adverse event reports and other complaints about compounded drugs, FDA proactively inspected additional pharmacies suspected of being at higher risk of making substandard products. FDA must follow up on findings from the inspections and must continue its inspection and enforcement efforts for the foreseeable future, as adverse events and seriously deficient sterile compounding practices continue to be discovered. FDA must also develop numerous regulations and other policy documents necessary to implement the new legislation and provide standards for the compounding industry. Without the resources for these activities, FDA will not be able to implement the new legislation and protect the public from substandard compounded products.

The DQSA provides FDA with additional authorities and responsibilities to strengthen oversight of compounding. The new law creates a new Section 503B in the Food, Drug, and Cosmetics (FD&C) Act. Under Section 503B, a compounder can become an "outsourcing facility." If certain conditions are met, an outsourcing facility will be able to qualify for exemptions from the FDA approval requirements and the requirement to label products with adequate directions for use. Outsourcing facilities are not exempt from the requirement to comply with Current Good Manufacturing Practice (cGMP), among other applicable requirements under the FD&C Act.

Under the DQSA, compounding firms that register as outsourcing facilities must pay a user fee and, under certain circumstances, a reinspection fee. However, because registration as an outsourcing facility is not required, FDA will not be able to rely on projected user fees to sustain the increased pace of inspections and investigations. Further, the DQSA explicitly states that compounding fees must supplement and not supplant non-user fee money for oversight of outsourcing facilities, and fees collected can only be used for oversight of outsourcing facilities. Therefore, the user fees collected cannot be used to oversee the thousands of pharmacies that will choose not to register as outsourcing facilities.

The return on investment for the pharmacy compounding initiative is expected to be high, delivering results that enable FDA to sustain and expand its mission of protecting and promoting the health and well-being of the American people. The investment of $25 million is necessary to successfully implement and support the activities for this initiative. This regulatory oversight will help prevent outbreaks and mitigate potential public health risks that could result in injuries or possible deaths to the American public.

The requested resources will be devoted to the following main activities.

Inspections and Enforcement: FDA must have an increased inspection and enforcement presence with regard to compounding pharmacies to protect the public health regardless of whether firms elect to register as outsourcing facilities and pay fees. FDA intends to continue conducting for-cause inspections in response to adverse event reports, product quality complaints, and State requests. In addition, the FY 2015 Budget seeks additional resources to conduct additional proactive inspections of high-risk pharmacies, as well as additional follow-up inspections of pharmacies identified as needing to take corrective actions during previous inspections. In addition to direct inspection resources, these inspections will require significant staff support for case management. This work will include writing the

[1] http://www.fda.gov/NewsEvents/Testimony/ucm348120.htm

inspection assignments, handling issues that arise during the inspections such as the need to obtain an administrative warrant to access records, assessing the inspection results, and bringing any necessary regulatory or enforcement actions.

Policy Development: FDA will be engaged in the development of policy documents establishing the framework for the oversight of pharmacy compounding. To implement Sections 503A and 503B, FDA intends to draft and publish additional regulations and guidances. Since Section 503A does not cover the compounding of animal drugs, FDA also intends to develop separate guidance that sets out its enforcement priorities with respect to animal drug compounding.

State Collaboration and Coordination: During hearings following the outbreak, Congress and other stakeholders criticized FDA for inadequately coordinating and collaborating with States that license pharmacies and oversee their day-to-day operations. The new law requires the Secretary to establish a mechanism to receive submissions from state boards of pharmacy concerning certain actions taken against compounding pharmacies or expressing concerns that a compounding pharmacy may be acting contrary to Section 503A. This section will be implemented in consultation with the National Association of Boards of Pharmacy (NABP). In addition, state boards of pharmacy must be notified when the Secretary receives certain state submissions or makes a determination that a compounding pharmacy is acting contrary to Section 503A. Given the states' regulatory role, FDA must expend more resources developing better cooperative relationships and communication tools to improve interactions with the states on pharmacy compounding. This also includes working with state inspectors on inspections of sterile compounding operations for compliance with appropriate quality standards. FDA also intends to enhance its intergovernmental relations activities to provide strategic oversight and strengthen relationships with state officials at all levels of state government, working with associations of state officials, and facilitating interactions with the FDA program offices with substantive program knowledge.

Proposed International Courier User Fee
FDA is proposing a new International Courier user fee to support activities associated with increased surveillance of FDA-regulated commodities at express courier hubs. Almost 80 percent, or $4.6 million, of this proposed fee will support imported medical product safety. The user fee will help provide FDA with the resources needed to keep pace with growing volume of imports that enter through international couriers and the increased cost of import operations to support international courier activities.

Food Safety (+$263 million)

The FY 2015 Budget provides a program level of $1.48 billion for food safety, which is $263 million above the FY 2014 Enacted level. Within this amount, FDA will invest $24 million in budget authority to further advance recent gains in food safety modernization through implementation of FSMA. This request also includes $255 million in proposed new user fees.

Food Safety Modernization
FDA will continue to make critical investments to implement FSMA. With the requested increase in budget authority, FDA will be able to increase the technical staffing and other capacity needed to develop guidance and provide technical assistance for industry and provide technical support for FDA inspectors, as well as planning and initial implementation of training for FDA and state inspectors. If the proposed user fee revenue is authorized and appropriated, FDA will be able to undertake the wider array of activities needed to fulfill the food safety modernization goals of FSMA, as outlined below, including comprehensive retraining of the federal and state inspection force to ensure inspection quality and consistency; training and technical assistance for small and mid-size growers and processors; and building the modern import oversight system mandated by FSMA. A central theme of these investments is supporting and leveraging the food safety efforts of both public and private partners to make the most effective use of available resources.

The implementation of the broad preventive controls framework mandated in FSMA will reduce instances of foodborne illness seen recently as a result of *E. coli* O157 contamination of pre-packaged salads, *Salmonella* and *Listeria* contamination of cheese products, and *Listeria* contamination in cantaloupe. Implementation will also reduce the large number of recalls seen yearly for undeclared allergens in food products. A lack of additional funding to support these efforts will limit FDA's ability to protect consumers by reducing or preventing these types of incidents, including the illnesses and deaths linked with them, and to minimize the market disruptions and economic costs inflicted by illness outbreaks and significant contamination incidents.

These resources will provide FDA with needed long-term funding for implementation of the modernized food safety Congress called for in enacting FSMA. The requested resources will be devoted to the following activities.

Standard Setting: FDA will finalize the most significant rulemakings mandated by FSMA, including preventive controls for human and animal food, produce safety, and foreign supplier verification.

Technical Support for FSMA Implementation: FDA will invest in staff and contractor support for ongoing FSMA guidance development, in collaboration with the food industry, federal and state partners, and other experts, to ensure that the requirements of the new FSMA rules are well understood as they apply to a wide range of commodities and processing operations. FDA will hire additional staff with food safety expertise in produce commodities and processing operations subject to new FSMA standards. FDA needs the technical capacity and expertise to support FDA and state inspectors and the food industry, and to work collaboratively with a broad range of food industry experts to ensure food safety standards are well understood, up-to-date, effective, and efficient.

Training: FDA will increase training and certification activities to ensure that federal, state, local, tribal, territorial, and international partners conducting food safety inspections and other food safety oversight activities have the skills and new orientation needed to conduct high quality and consistent oversight under FSMA's new prevention-oriented and systems-based public health regulatory framework.

Federal-State Integration: In addition to supporting training for state partners, this funding also supports state capacity building, FDA-state joint work planning and data sharing, and collaborative agreements, such as the Manufactured Food Regulatory Program Standards, which allows for the development of a uniform basis for measuring and improving the performance of state manufactured food regulatory programs.

Risk Analysis: FDA will increase data gathering and analytical capacity to support risk-based priority setting and resource allocation, including automating and expediting risk analysis and integration of risk information into decision-making tools. FDA will continue to adapt these tools for use by the public and industry, which will increase the precision of risk evaluation of FDA-regulated commodities and associated hazards.

Antimicrobial Resistance: FDA will implement its initiative to phase out animal production uses of medically important antimicrobial drugs and bring remaining legitimate animal health uses under veterinary supervision. To support this initiative, FDA will collect use data and conduct other research to better understand antimicrobial drug use practices in animals and the public health impacts on antimicrobial resistance. FDA will use this funding to enhance methods for characterizing bacteria, conduct studies to better understand drug effects on bacteria, and develop approaches to monitor and assess drug use and antimicrobial resistance trends.

Proposed Food Safety User Fees
FDA is proposing two user fees for Food Import ($169 million) and Food Facility Registration and Inspection ($60 million) to support implementation of FSMA, including improving FDA's import process and modernizing FDA's inspection system.

With the proposed import user fee, FDA will implement the FSMA mandate for a modern-prevention-oriented import oversight system that ensures imported food meets the same high safety standards as domestically produced food, The new import fees target activities associated with implementing the Foreign Supplier Verification Program mandated by FSMA, including recruiting and training FDA import staff to assess the adequacy of importer supply chain management and verification programs. To ensure that the new import oversight system does not impede trade, FDA will also invest in the staff, information technology and process improvements needed to make timely import entry decisions. These fees will enhance both the safety protections for imported food and feed and the efficiency and speed of food and feed entry decisions, thus supporting international trade in safe food and feed.

Revenue from registration fees will target new and improved activities required by FSMA to modernize FDA's inspection system. The fees will enable FDA to increase the effectiveness of inspections through adoption of preventive controls, training of personnel to inspect against the new prevention standards, and developing new ways to educate and inform industry. Fees will also support improvements in food and feed safety science and risk analysis, so that knowledge of the methods of food and feed contamination can better prevent outbreaks, and ensure that resources are better focused on areas of greatest risk.

Proposed Food Contact Substance Notification User Fee
FDA is proposing a new user fee of $5.1 million to ensure that the Food Contact Substance Notification (FCN) program operates more predictably by providing a stable, long-term source of funding to supplement budget authority appropriations. FDA has statutory responsibility for the safety of all food contact substances in the United States. The Food and Drug Administration Modernization Act established a premarket notification process for food contact substances, known as the FCN program. The FCN process is simpler, more efficient, and requires fewer resources than the alternative food additive petition process. However, Section 409(h)(5) of the FD&C Act specifies that the FCN program can operate only if adequately funded. The proposed user fee will provide greater predictability of program funding and operations.

Proposed Cosmetics User Fee
FDA is proposing a new user fee of $19.5 million to support FDA cosmetic safety responsibilities. The FD&C Act does not authorize FDA to collect user fees to support the Cosmetics Program. Consequently, the FDA Cosmetics Program is challenged to keep pace with industry growth in all areas. The proposed user fees will improve FDA's capacity to promote greater safety and understanding of cosmetic products.

Proposed International Courier User Fee
FDA is proposing a new International Courier user fee to support activities associated with increased surveillance of FDA-regulated commodities at express courier hubs. Approximately 20 percent, or $1.2 million, of this proposed fee will support imported food safety. The user fee will help provide FDA with the resources needed to keep pace with growing volume of imports that enter through international couriers and the increased cost of import operations to support international courier activities.

Medical Countermeasures (-$48 thousand)

The FY 2015 Budget provides a program level of $24.5 million for continuation of Medical Countermeasures activities across FDA program, which is $48 thousand below the FY 2014 Enacted level due to decreased rent costs. FDA will continue to promote the development of medical countermeasures by establishing clear regulatory pathways for medical countermeasures, instituting effective regulatory policies and mechanisms to facilitate timely access to available medical countermeasures, and advancing medical countermeasures regulatory science.

NON-ADDS:

Infrastructure (+$6 million)

Within the funding for medical product and food safety, and medical countermeasures, FDA requests a program level increase of $5.8 million for infrastructure. Infrastructure includes GSA Rental Payments, Other Rent and Rent Related costs, and White Oak Consolidation.

Rental Payments
FDA requests a $20.6 million program level increase for GSA Rental Payments and Other Rent and Rent Related costs. The rental properties that provide office and laboratory space are essential facilities that allow FDA to perform its vital public health mission. The resources requested for GSA Rent cover the cost of rental payments to GSA for FDA's six million square feet of rented office and laboratory space, as well as payments to the Department of Homeland Security for guard services and security systems at these facilities. Other Rent and Rent-Related activities includes commercial rent and rent-related charges that are not part of the GSA Rental account.

White Oak Consolidation
The FY 2015 Budget provides a program level of $47.1 million, $14.8 million below the FY 2014 Enacted level. The funding level supports ongoing and expanded operational and logistical functions for 9,000 employees on the White Oak Campus, including services vital to support of medical product safety, such as the new Life Sciences-Biodefense Complex.

Current Law User Fees (+$75 million)

Within the funding for medical product and food safety, FDA requests a$75.4 million increase for current law user fees, which will allow FDA to fulfill its mission of protecting the public health and accelerating innovation in the industry. The user fees collected will support the review and surveillance of human and animal drugs, medical and mammography devices, food and feed, color additives, export certification, and tobacco products. The request includes statutorily mandated increases for many existing programs, which will expand the available options for treating and curing diseases and will fund strategies to reduce the burden of illness and death caused by tobacco products. Note that some of the amount requested supports infrastructure costs associated with current law user fee programs.